K022821

SECTION C - 510(K) SUMMARY

NOV 15 2002

Ideatrics, Inc.
7341 South Meadow Court
Boulder, Colorado 80301
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contact: James W. Heller, President

Submitted: August 19, 2002

Trade Name: Aragon Wiring System Wire Cartridge (models I0007, I0008, I0009, I0010, I0011 and I0012)

Common Name: Stainless Steel Wire for Mandibular Fixation

Classification: Class II, Dental classification panel, product code DZK, Intraosseous Fixation Wire, CFR section 872.4880, Intraosseous Fixation Screw or Wire

Predicate Devices: Intraosseous Fixation Wire by Synthes, Biomet-Kirschner, Stryker Instruments, Dupuy International Ltd., Zimmer, Inc. and Mathys Medical Ltd.

Device description: 22, 24 and 26 gauge annealed 316LVM stainless steel wire in 5 ft. coils packaged in a thermoplastic cartridge that mounts on forceps

Intended Use: Stabilization of mandibular fractures

Technical differences from Predicate devices: Wire is identical to predicate devices. It is packaged in a 5 ft. length in a single use cartridge that mounts on forceps. In predicate devices the wire is packaged in a 75-675 ft. length on a reusable spool that is kept on the surgical instrument tray.

Conclusion: The technical differences between this product and the predicate devices do not adversely affect safety or efficacy.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 1 5 2002

Mr. James W. Heller
President
Ideatrics, Incorporated
7341 South Meadow Court
Boulder, Colorado 80301

Re: K022821
Trade/Device Name: Aragon Wiring System
Regulation Number: 21 CFR 872.4880
Regulation Name: Intraosseous Fixation Screw or Wire
Regulatory Class: II
Product Code: DZK
Dated: August 19, 2002
Received: August 26, 2002

Dear Mr. Heller:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K022821

Device Name: Aragon Wiring System

Indications For Use:

This device is used in surgery for the application of wires to the jaws of adults and children. The device can be used to directly wire bony segments together, or for the application of arch bars to the teeth for stabilization of bony fragments or wiring the teeth together (maxillomandibular fixation).

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use____ OR Over-The-Counter Use
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K022821